

National Influenza Vaccine Summit Newsletter



Issue 1 / June 2006

The American Medical Association (AMA) and the Centers for Disease Control and Prevention (CDC) co-sponsor the National Influenza Vaccine Summit (The Summit). The Summit is an action-oriented entity with over 400 members who represent over 100 public and private organizations with an interest in addressing and resolving influenza and influenza vaccine issues.

Beginning with this first issue, the Summit will publish and distribute monthly bulletins to update partners about recent developments related to the production, distribution, and administration of influenza vaccine. All recipients of this newsletter are encouraged to distribute each issue widely to colleagues, members, and constituents. The National Influenza Vaccine Summit Newsletter will replace the CDC Influenza Bulletin.

Second National Influenza Vaccine Summit for 2006

The objective for the upcoming summit in Chicago, June 22 is to discuss, develop, and implement a plan to increase utilization of influenza vaccine for the 2006–07 influenza season. Focus will be given to vaccination of priority groups, contacts and the general public, helping health care providers to better promote influenza vaccination, and communication strategies to facilitate increased utilization of influenza vaccine. The summit will also provide an update on the 2006-2007 Influenza Vaccine Production, Supply and Distribution.

Online Summit Materials

Summit materials will be available online at www.ama-assn.org/ama/pub/category/13732.html.

Previous summit minutes and materials are also available at this website.

Influenza Vaccine Supply and Production

2005-06 Influenza Season

The 2005-06 influenza season showed that the amount of projected vaccine and the timing of its actual availability are critical factors in the success of a seasonal influenza vaccination program. Though Chiron projected producing 25 million doses of vaccine during the season,

only about half of what was originally projected was produced. Because vaccine orders are placed early in the season, there was a large gap between doses ordered and doses produced, and Chiron's distributors were unable to completely fill orders of this product. As a result, some providers were late in receiving Chiron vaccine and received none or only a small percentage of their orders. The tiered vaccination strategy recommended by CDC in September 2005 to prioritize anticipated limited vaccine may have complicated the situation because many high risk persons were not able to be vaccinated prior to October 24 due to delays in vaccine distribution.

Perceptions about which groups received influenza vaccine during the 2005-06 season varied. Because community vaccine providers and clinics are so visible to private providers and the general public, it was perceived that they were able to obtain as much vaccine as they ordered and wanted. This was also exacerbated by the perception that physicians were unable to receive the vaccine that they ordered and wanted for their patients. A provider survey of influenza vaccine questions for the 2005-06 influenza season revealed that at least 50% in all groups reported that they received more than 40% of their influenza vaccine orders except family physicians (43%). More government providers, including state and local federal immunization grantees (86%) and county and city health departments (70%) received more than 80% of their orders than providers in other groups.

A Gallup survey revealed that patients relied primarily on doctors offices and HMOs for their influenza vaccine—not their local grocery or drug stores. This vaccine data obtained from 900 individuals showed that 39% who obtained a flu shot during the 2005-06 influenza season received the shot from a doctors office or HMO. The remaining respondents received influenza vaccination from the workplace (17%), other health clinics or health centers (10%), grocery stores or pharmacies (10%), health department (8%), hospital (6%) senior or recreation center (4%), other (4%), and school (2%). Improved communication strategies may help to prevent misperceptions about vaccine supply and distribution during upcoming influenza seasons. This focus on communicating accurate and timely information may also help to build provider as well as patient confidence and trust in the supply, production and distribution of influenza vaccine.

For the 2006-07 influenza season, contingency plans including communication strategies are in place in the event that influenza vaccine is delayed or the supply is insufficient. In addition, promoting influenza vaccine utilization will help to optimize health protection of the US population and to minimize waste of vaccine. These goals will be discussed further during the second 2006 national influenza vaccine summit meeting.

Projection of the 2006-07 Influenza Vaccine Supply

As of June 9, 2006, influenza vaccine manufacturers project that approximately 100 million doses of influenza vaccine will be available in the U.S. for use during the 2006-07 influenza season. This amount represents approximately 16% more doses than were available for the 2005-06 season. An additional 15 million doses may be available if a new vaccine is licensed in 2006.

Also as of June 9, 2006, sanofi pasteur projects that 8 million to 9 million doses of thimerosal-free vaccine in pre-filled syringes or vials will be produced for the 2006-07 influenza season. The majority of this vaccine will be in 0.25 mL syringes (indicated for ages 6-35 months) with the remainder in 0.5 mL vials or syringes (indicated for ages 36 months and older). In addition, GSK's influenza vaccine for adults 18 years of age and older is preservative-free (trace thimerosal) vaccine and Novartis (formerly Chiron) has a preservative-free (trace thimerosal) preparation for persons 4 years of age and older. The nasal influenza vaccine, FluMist, also is thimerosal-free.

GlaxoSmithKline (GSK) submitted a Biologics License Application (BLA) to the FDA for FluLaval, a seasonal, inactivated influenza vaccine, and hopes to receive approval for use in persons aged 18 years and older in time for the 2006-07 influenza season. If approved, GSK projects up to 15 million doses of FluLaval will be available in the US for the 2006-07 influenza season.

Influenza Virus Vaccine 2006-2007

The FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) recommended in February 2006 that vaccines to be used in the 2006-2007 season in the U.S. contain the following:

- an A/New Caledonia/20/99 (H1N1)-like virus;
- an A/Wisconsin/67/2005 (H3N2)-like virus (A/Wisconsin/67/2005 and A/Hiroshima/52/2005 strains);
- a B/Malaysia/2506/2004-like virus (B/Malaysia/2506/2004 and B/Ohio/1/2005 strains)

The influenza vaccine composition to be used in the 2006-2007 season in the U.S. is identical to the recommendation from the World Health Organization on February 15, 2006.

Influenza Vaccine Distribution and Administration

Ordering Influenza Vaccine

Much of the influenza vaccine was pre-booked early this year. Providers should contact distributors and local vendors about remaining supply. Additional doses may be available if a new vaccine is licensed in 2006.

New ACIP Recommendation for Routine Influenza Vaccination of Children 6-59

In February 2006, the Advisory Committee on Immunization Practices (ACIP) voted to extend routine annual influenza vaccination recommendations to include all healthy children aged 6-59 months. Recommendations are reviewed by the Director of CDC and the Department of Health and Human Services (HHS). They become official when published in CDC's Morbidity and Mortality Weekly Report (MMWR).

During the 2006-2007 influenza season, all providers may not have sufficient vaccine supply in the preparations indicated for this age group. If a provider has insufficient vaccine for this age group, CDC recommends that healthy children aged 6-23 months should be prioritized for receiving vaccine because they are at increased risk for hospitalization compared with children over 24 months of age.

Anticipated Shortage of Vaccine for Children Three Years of Age

CDC anticipates that many providers will be unable to obtain sufficient vaccine to vaccinate all children who are 3 years of age. Because sanofi pasteur is the only supplier of vaccine that can be administered to 3-year-old children and all of sanofi pasteur's vaccine for use in ages 3 years and above was pre-booked in January 2006 (prior to the ACIP recommendation to expand annual vaccination to children 24 to 59 months of age), providers are unable to make additional purchases of this vaccine. Vaccines for children less than 3 years of age and for those 4 years of age and older are still available for purchase; children younger than 3 years of age can be vaccinated with the 0.25 ml preparation from sanofi pasteur and children 4 years of age and older can be vaccinated with Novartis vaccine. In addition, another vaccine that can be used in healthy children 5 years of age and older is the intranasal vaccine produced by MedImmune. In general, the annual supply of influenza vaccine and the timing of its distribution cannot be guaranteed in any year. At the current time, we have no information to suggest that production problems will result in a delay of vaccine that has been ordered. CDC anticipates adequate supplies of vaccines for older children and adults. However, influenza vaccine distribution delays or vaccine shortages remain possible in part because of the inherent critical time constraints in manufacturing the vaccine given the annual updating of the influenza vaccine strains.

JCAHO Announces Infection Control Standard to Include Influenza Vaccinations to Staff

On June 13, 2006, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) announced the approval of an infection control standard requiring accredited organizations to offer influenza vaccinations to staff, volunteers and licensed independent practitioners with close patient contact. This standard will become an accreditation requirement beginning January 1, 2007, for the Critical Access Hospital, Hospital and Long Term Care accreditation programs.

JCAHO developed the standard in response to recommendations by CDC making the reduction of influenza transmission from health care professionals to patients a top priority in the United States. While the CDC has urged annual influenza vaccination for health care workers since 1981, the CDC's "*Morbidity and Mortality Weekly Report*" published earlier this year calls for stronger steps to increase influenza vaccination of health care workers. Despite the recommendations, the vaccination rates as measured by the CDC remain low.

Health care-associated transmission of influenza has been documented among many patient populations in a variety of clinical settings. Typically, fewer than 40 percent of health care workers are immunized each year. The new JCAHO standard requires organizations to:

- Establish an annual influenza vaccination program that includes at least staff and licensed independent practitioners;
- Provide access to influenza vaccinations on-site;
- Educate staff and licensed independent practitioners about flu vaccination; non-vaccine control measures (such as the use of appropriate precautions); and diagnosis, transmission and potential impact of influenza;
- Annually evaluate vaccination rates and reasons for non-participation in the organization's immunization program; and
- Implement enhancements to the program to increase participation.

The full JCAHO press release which includes the text above is available at www.jointcommission.org/NewsRoom/NewsReleases/nr_06_13_06.htm.

Influenza vaccine preparations and their indications as licensed by the FDA

TABLE. Influenza Vaccine Manufacturers for the 2006-07 Influenza Season

Manufacturer	Vaccine	Formulation	Thimerosal preservative	Age indication
sanofi pasteur, Inc.	Fluzone®, Inactivated TIV	Multi-dose vial	Yes	≥ 6 months
		Single-dose pre-filled 0.5 mL syringe or vial	None	≥ 36 months
		Single-dose pre-filled 0.25 mL syringe	None	6-35 months
MedImmune Vaccines, Inc	FluMist™ LAIV	Single-dose sprayer	None	Healthy persons 5-49 years
Novartis Vaccine (formerly Chiron Corporation)	Fluvirin™ Inactivated TIV	Multi-dose vial	Yes	≥ 4 years
		Single-dose 0.5 mL syringe	<1µg Hg/0.5mL dose), preservative free	≥ 4 years
GlaxoSmithKline, Inc.	Fluarix™ Inactivated TIV	Single-dose pre-filled syringe 0.5 mL	<1.25µg Hg/0.5mL dose, preservative free	≥ 18 years

CDC Influenza Vaccine Bulletins

Previous influenza vaccine bulletins are available on the CDC website at www.cdc.gov/flu/professionals/flubulletin.htm.

Upcoming Events

National Association of County and City Health Officials (NACCHO) Annual Conference, July 26–28, San Antonio, Texas, www.naccho.org/conferences/NACCHOannual06/

Seventh National Conference on Immunization Coalitions, August 9–11, 2006, Denver, Colorado, www.seeuthere.com/rsvp/invitation/invitation.asp?id=m2c666-455170415278

National Adult Immunization Awareness Week, September 24–30, 2006, Nationwide, www.cdc.gov/nip/events/naiaw/